September 15, 2021

Lumen Biomedical, Inc.
Maria Brittle
Director, Regulatory Affairs
14505 21st Ave. North
Suite 212
Plymouth, Minnesota 55447

Re: K071529
Trade/Device Name: Xtract Catheter System
Regulation Number: 21 CFR 870.5150
Regulation Name: Embolectomy catheter
Regulatory Class: Class II
Product Code: QEZ

Dear Maria Brittle:

The Food and Drug Administration (FDA) is sending this letter to notify you of an administrative change related to your previous substantial equivalence (SE) determination letter dated August 10, 2007. Specifically, FDA is updating this SE Letter because FDA has created a new product code to better categorize your device technology.

Please note that the 510(k) submission was not re-reviewed. For questions regarding this letter please contact Gregory O'Connell, OHT2: Office of Cardiovascular Devices, (301) 796-6075, Gregory.Oconnell@FDA.HHS.gov.

Sincerely,

Gregory W. O'connell -S
Digitally signed by Gregory W. O'connell -S
Date: 2021.09.15 10:19:26 -04'00'

Gregory O'Connell
Assistant Director
Plaque Modification Devices Team
DHT2C: Division of Coronary and Peripheral Intervention Devices
OHT2: Office of Cardiovascular Devices
Office of Product Evaluation and Quality
Center for Devices and Radiological Health

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

AUG 10 2007

Lumen Biomedical , Inc.
c/o Maria E. Brittle, PhD
Director Regulatory Affairs
14505 21st Avenue North, Suite 212
Plymouth, MN 55447

Re: K071529
Xtract™ Aspiration Catheter
Regulation Number: 21 CFR 870.5150
Regulation Name: Embolectomy Catheter
Regulatory Class: II (two)
Product Code: DXE
Dated: July 20, 2007
Received: July 23, 2007

Dear Dr. Brittle:

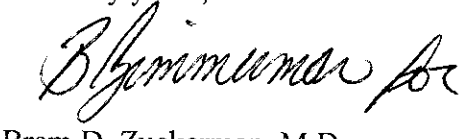
We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.
This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Office of Compliance at (240) 276-0120. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (240) 276-3150 or at its Internet address http://www.fda.gov/cdrh/industry/support/index.html.

Sincerely yours,



Bram D. Zuckerman, M.D.
Director
Division of Cardiovascular Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

## Indications for Use

510(k) Number (if known): K071529

Device Name: Xtract® Catheter System

Indications for Use:

The Xtract® Catheter System is indicated for the removal of fresh, soft emboli and thrombi from vessels in the arterial system.

Prescription Use ___X___ (Part 21 CFR 801 Subpart D) AND/OR Over-The-Counter Use _____ (21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE OF NEEDED)

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Concurrence of CDRH, Office of Device Evaluation (ODE)

B Chronister

(Division Sign-Off)
Division of Cardiovascular Devices
510(k) Number K071529

K071529

LUMEN BIOMEDICAL

AUG 10 2007

**Lumen Biomedical, Inc.**

**14505 21st Avenue North, Suite 212**
**Plymouth, MN 55447**
**(763) 577-9600 Business**
**(763) 557-1044 Fax**

## 510(k) Summary

| | |
|---|---|
| **Contact Person:** | Maria Brittle<br>Director Regulatory Affairs |
| **Summary Date:** | June 4, 2007 |
| **Product Trade Name:** | Xtract™ Catheter System |
| **Common Name:** | Catheter, embolectomy<br>Catheter, thrombectomy |
| **Classification Name:** | Catheter, embolectomy |
| **Predicate(s):** | LBI Aspiration Catheter (K053372) |
| **Intended Use:** | The Xtract™ Catheter System is indicated for the removal of fresh, soft emboli and thrombi from vessels in the arterial system. |
| **Device Description:** | The Xtract Catheter System consists of one (1) Catheter, one (1) Extension Tube with Stopcock, two (2) 30cc Aspiration Syringes, and one (1) 40μm Strainer. The catheter is a single-use, 0.014" guidewire compatible, temporary intravascular extraction and aspiration catheter. It has a distal radiopaque tip marker, a varying stiffness shaft, a rapid exchange port, and a proximal luer-lock hub. |
| **Indication for Use:** | The Xtract Catheter System is indicated for removal of fresh, soft emboli material and thrombi from vessels in the arterial system. |
| **Safety & Performance:** | The results of the *in vitro* bench and biocompatibility testing demonstrated the system is equivalent to the predicate device. |
| **Conclusion:** | This product is substantially equivalent[1] and acceptable for the intended use. |

[1] This document uses the term "substantial equivalent" as intended in 21 CFR 807.87 and not as defined in Title 36 of the U.S. Code.